REMARKS

Claims 16, 19-30, 37-40, and 43-50 are currently pending in the present application. In the present response, Applicant has amended Claims 16, 19, 21-22, 27-30, 37, 44-46, and 48-49. Claims 1-15, 17-18, 31-36, and 41-42 were previously canceled. Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

I. Claim Rejections – 35 U.S.C. § 103

Claims 16, 19-30, 38-39, and 48-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,651,775 issued to Walker et al. ("Walker") in view of U.S. Patent No. 6,170,746 issued to Brook et al. ("Brook").

a. Claim 16

Amended Claim 16 recites:

> 16. A method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:
>
> generating a unique tracking code for a single medical device loaded with a drug, wherein said unique tracking code is unique as to said single medical device loaded with a drug,
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> receiving data associated with said single medical device loaded with a drug, the received data including information associated with an action performed relating to the single medical device loaded with a drug, the action including at least one of preparing the single medical device loaded with a drug, administering the single medical device loaded with a drug to a patient, and disposing of the single medical device loaded with a drug,
>
> storing the data on a storage device with the unique tracking code for the single medical device loaded with a drug to form at least one record uniquely tied to the single medical device loaded with a drug,
>
> receiving a request for information regarding the single medical device loaded with a drug, the request including said unique tracking code,
>
> retrieving stored data from the at least one record including said unique tracking code stored on said storage device, and
>
> outputting the stored data in response to the request.

First, as admitted by the Examiner, Walker does not teach or suggest the subject matter of Claim 16. In particular, the Examiner states that Walker does not teach or suggest "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to said single source," "storing data in association with said tracking code on a storage device," and "retrieving the

stored data from said storage device using said tracking code," as recited in Claim 16. Therefore, for at least these reasons, Walker fails to disclose the subject matter of amended Claim 16.

Brook does not solve the deficiencies of Walker. First, Brook fails to teach or suggest "generating a unique tracking code for a single medical device loaded with a drug, wherein said unique tracking code is unique as to said single medical device loaded with a drug," as recited in amended Claim 16. In general, Brook discloses methods and systems for tracking the type and quantity of drugs at a particular location (col. 3, lines 8-13). In particular, Brook discloses a picking routine that is performed when drugs are to be moved from a first location (e.g., a distribution location) to a second location (e.g., a specific nurse's station) (col. 6, lines 56-62). The first step of the picking routine includes retrieving station records and displaying the stations represented by the station records in a selection box to a user (FIG. 3A, col. 6, lines 62-66). Once the user selects a station from the selection box, the system retrieves the drugs assigned to the selected station (e.g., stored in a drugs or narcotics record) along with any pick-lists specified for the selected station (col. 6, lines 66-67 - col. 7, lines 1-5). The pick-lists specify the amount of drugs that should be picked up for the selected station (col. 7, lines 5-8).

To pick up a drug listed on a pick-list for the selected station, the system disclosed in Brook displays information identifying the drug to be picked up and prompts the user to select the identified drug (col. 8, lines 35-38). To select the identified drug, the user, using a portable barcode scanner, "scans a barcode typically contained on a shelf supporting the drug . . . [or] on a drug container itself, where the barcode represents the drug identified in the displayed prompt" (col. 8, lines 41-45). As described in Brook, the barcode scanned by the user contains "National Drug Code (NDC) information that identifies a drug, i.e., the drug's name and its strength" (col. 5, lines 51-54). After the user scans the barcode, the system disclosed in Brook compares the scanned NDC data with the NDC data contained in the pick-list (col. 8, lines 52-55). If the NDC data does not match, the system displays a message to the user that the user has selected the wrong drug (i.e., the scanned drug is not the drug indicated in the pick-list for the selected station) (col. 8, lines 55-61). If, however, the NDC data matches, the system prompts the user to enter the quantity of the scanned drug that the user is picking up for the selected station (col. 8, lines 66-67 – col. 9, lines 4). After the user inputs the quantity to be picked up, the system disclosed in Brook updates the drugs record for the selected station based on the quantity specified by the user (col. 9, lines 30-33) and generates labels for the picked-up drugs that specify the destination of the picked-up drugs (i.e., the selected station) (col. 9, lines 40-45). The labels also include the "barcoded NDC data for the drug so that the drug can be tracked by a portable scanning and printing system 20 at its destination location" (col. 9, lines 45-48).

Clearly, the bar codes disclosed in Brook only specify a drug type but do not uniquely identify a single medical device loaded with a drug, such as a capsule, a vial, a box, a syringe, etc. For example, if a hospital has three vials of morphine of the same strength in their drug supply room and uses the system disclosed in Brook, each vial would have the same bar code containing the same NDC. Similarly, if a hospital has three capsules of aspirin each individually-packaged with its own label, each label used in the system disclosed in Brook would include the same bar code with the same NDC code. The NDC code by its very nature provides a universal identifier for a particular type of drug, but does not provide any type of information that uniquely tracks a single instance of a medical device loaded with a specific drug.

Moreover, because the Brook system assigns each type of drug the same bar code with the same NDC code, the system disclosed in Brook has no way to track actions performed relating to a single instance of medical device loaded with a drug. Therefore, Brook does not generate or access a unique record associated with a single instance of a medical device loaded with a drug. For example, if a user moves two vials of morphine from a first location to a second location, the system disclosed in Brook only knows the quantity of vials at the first location and at the second location. The system in Brook has no way of knowing any details about an individual vial moved from the first location to the second location. If a hospital was alerted that particular vials of morphine recently delivered to a hospital were tainted, the hospital, using the system disclosed in Brook, would know how much morphine was at each station throughout the hospital but would be unable to track or retrieve any information specifying where particular vials of morphine were currently located in the hospital because each vial is marked with an identical bar code and no information is stored in a record uniquely tied to an individual vial.

Therefore, Brook clearly at least does not teach or suggest "generating a unique tracking code for a single medical device loaded with a drug, wherein said unique tracking code is unique as to said single medical device loaded with a drug," as recited in amended Claim 16. In addition, because Brook does not uniquely track a single instance of a medical device loaded with a drug, Brook also does not teach or suggest "receiving data associated with said single medical device loaded with a drug, the received data including information associated with an action performed relating to the single medical device loaded with a drug, the action including at least one of preparing the single medical device loaded with a drug, administering the single medical device loaded with a drug to a patient, and disposing of the single medical device loaded with a drug," and "storing the data on a storage device with the unique tracking code for the single medical device loaded with a drug to form at least one record uniquely tied to the single medical device loaded with a drug." Furthermore, Brook does not teach or suggest "receiving a request for information regarding the single medical device loaded with a drug, the request including said unique tracking code," "retrieving stored data from the at least one record including said unique tracking

code stored on said storage device," and "outputting the stored data in response to the request," as also recited in amended Claim 16.

Accordingly, for at least the reasons set forth above, Walker and Brook, taken individually or in combination, fail to teach or suggest the subject matter of amended Claim 16. Accordingly, Claim 16 is allowable. Dependent Claims 19-26 and 38, which depend from independent Claim 16, are also allowable for at least the reasons set forth above.

b. Claim 27

Amended Claim 27 recites:

27. A method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

preparing a single source of a drug to be administered to a patient, wherein said single source of a drug includes an individual drug and an individual medical device,

affixing said single source in a cradle,

providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle, wherein said unique tracking code is unique as to said single source,

identifying data associated with a first quantity of said drug in said single source and said patient,

storing said data in association with said unique tracking code on a storage device,

administering a second quantity of said drug to said patient from said single source,

disposing of said single source after administration of said drug to said patient;

updating said first quantity of said drug stored in the storage device with the unique tracking code based on the second quantity of said drug, and

retrieving said data from said storage device using said unique tracking code,

wherein said data, retrieved by the tracking code from the storage device, tracks said source from preparation of said source containing said drug to disposing of said source, wherein said unique tracking code conveys no information other than the identity of the tracking code.

As described above with respect to Claim 16, Brook and Walker fail to teach or suggest a unique tracking code that uniquely identifies a single instance of a medical device loaded with a drug. Therefore, Brook and Walker also fail to teach or suggest "providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle, wherein said unique tracking code is unique as to said single source," as recited in Claim 27.

As also described above with respect to Claim 16, Brook and Walker fail to teach or suggest storing data associated with actions performed relating to a single instance of a medical device loaded with a drug with the unique tracking code to form a unique record for the single medical device loaded with a drug. Therefore, Brook and Walker also clearly fail to teach or suggest "storing said data in association with said unique tracking code on a storage device," "updating said first quantity of said drug stored in the storage device with the unique tracking code based on the second quantity of said drug," and "retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said source from preparation of said source containing said drug to disposing of said source," as recited in Claim 27. Furthermore, Claim 27 also recites that the "unique tracking code conveys no information other than the identity of the tracking code." As discussed above, the barcode disclosed in Brook is not a unique tracking code for a single source. In addition, the barcode disclosed in Brook provides the National Drug Code. Therefore, the bar code disclosed in Brook also discloses additional information about the type of drug.

Accordingly, for at least the reasons set forth above, Walker and Brook, taken individually or in combination, fail to teach or suggest the subject matter of independent Claim 27. Accordingly, Claim 27 is allowable. Dependent Claims 28-30 and 39, which depend from independent Claim 27, are also allowable for at least the reasons set forth above. In addition, independent Claims 37, 44, and 48 include one or more similar elements as Claim 27. Therefore, independent Claims 37, 44, and 48 are also allowable for at least the reasons set forth above with respect to Claim 27. Dependent Claims 40 and 43, 45-47, and 49-50 depend from Claims 37, 44, and 48, respectively, and, therefore, are also allowable.

II. Conclusion

In light of the above, Applicant believes that the application is in condition for allowance and respectfully requests that the Examiner issue a timely Notice of Allowance. Applicant also requests that the Examiner telephone the attorneys of record in the event a telephone discussion would be helpful in advancing the prosecution of the present application.

Respectfully submitted,

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